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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,866	03/13/2001	Ivan K. Chu	7933.208USU1	2518

23552 7590 05/27/2003

MERCHANT & GOULD PC  
P.O. BOX 2903  
MINNEAPOLIS, MN 55402-0903

EXAMINER
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ZEMAN, MARY K

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/804,866

Applicant(s)

CHU ET AL.

Examiner

Mary K Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-15 are pending in this application. The preliminary amendments of 3/13/01 and 07/03/01 have been entered.

#### ***Priority***

The examiner acknowledges the claim to priority to a provisional application 60/193,208, filed 3/30/2000. However, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

#### ***Information Disclosure Statement***

The IDS filed 12/26/01 has been entered and considered. An initialed copy of the form PTO-1449 is included with this action.

#### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. see, at least page 15, line 28.

#### ***Claim Objections***

Claim 2 is objected to because of the following informalities: Claim 2 does not end in a period, as required. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 1, it is unclear if the proteins must also be argentinated from the phrase "argentinated peptides or proteins". It would appear by the method steps that it should be, but it is not specifically recited. Further, the steps of the method are solely performed on oligopeptides, and not peptides or proteins as recited in the preamble. The three terms (oligopeptide, peptide and protein) are not necessarily synonymous. It is suggested that a single term be used for clarity.

Further in claim 1, two spellings of "argentinated" are used. It is unclear which is correct. Line 1 sets forth "argentinated" while line 4 sets forth "argentiatiated".

Claim 1 appears to be missing steps, or functions. It would appear that the process must be iterated more than once to obtain the necessary doublet or triplet patterns, and to deduce sequence information. However, such steps are not set forth.

In claim 3, the term "comprises" is open claim language that is not considered to limit the length of the oligopeptide. The term "consists of" would limit the oligopeptide to the desired 3 to 10 amino acids.

In claim 5, it is unclear where the values for the formulae are to be derived. The steps of claim 1, from which claim 5 depends, do not clearly result in the determination of the values required for the further limitations in claim 5. Further, what is searched, and how does the use of the resulting formulas identify a cleaved residue?

In claim 7, both doublet and triplet patterns are required, while in claim 1, from which claim 7 ultimately depends, either can be used, and both are not required. This is confusing.

It is unclear where the limitation of claim 8 should be placed within the method steps of claim 1. Claim 1 does not recite a step of collecting product ion spectra, such that the further limitation of those conditions by claim 8 is confusing.

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The limitations of claim 9 lack antecedent basis in claim 1. Claim 1 does not list or require a mass spectrometer. The limitations in claim 9 as to the type of mass spectrometer lack basis in claim 1.

In claim 10, line 1, it is unclear if the proteins must also be argentinated from the phrase "argentinated peptides or proteins". It would appear by the method steps that it should be, but it is not specifically recited. Further, the steps of the method are solely performed on oligopeptides, and not peptides or proteins as recited in the preamble. The three terms (oligopeptide, peptide and protein) are not necessarily synonymous. It is suggested that a single term be used for clarity.

In claim 11, the term "comprises" is open claim language that is not considered to limit the length of the oligopeptide. The term "consists of" would limit the oligopeptide to the desired 3 to 10 amino acids.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al. (1999).

The claims are drawn to methods of sequencing small peptide through mass spectrometry, wherein the peptides are labeled with silver nitrate to become argentinated polypeptides. The claims set forth conditions for the collection of the product ion spectra, as well as limitations as to the computer programs used to analyze the data.

Chu et al. (Chu, I.K. et al. Anal. Chem., 71 (13), 2364 -2372, 1999. from PTO-1449) disclose the same methods and computer programs as those being claimed. At page 2366, is the following: "Sequencing. For sequencing, product-ion spectra of the  $[M + Ag]^+$  ion collected under  $E_{cm} = 1.5, 2.0, 2.5$ , and  $3.0$  eV were typically summed to yield a composite spectrum that exhibited a wide range of abundant product ions. Alternatively, product-ion spectra were

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acquired with a linear  $m/z$  dependent  $E_{cm}$  function to maximize the number of observable sequence-relevant product ions. The peak abundance file of the spectrum for sequencing, after elimination of peaks below a certain user-defined threshold, was read into a custom search algorithm written in Visual Basic which looked for the triplet peak pattern of  $(m/z)_1$ ,  $(m/z)_2 = (m/z)_1 - 18.0$ , and  $(m/z)_3 = (m/z)_2 - 28.0$  as well as the doublet pattern of  $(m/z)_2$  and  $(m/z)_3$ , all to within  $\pm 0.5$   $m/z$  unit. Triplet and doublet peak patterns that were found were imported into a commercially available spreadsheet program (Excel). A user-defined threshold (typically 10% of maximum) was used to filter out noise. The differences in  $m/z$  values of neighboring triplets were used to search for cleaved amino acid residues or combinations of them by means of AminoCal, a shareware available on the World Wide Web.<sup>44</sup> For peptides that have C-terminal lysine and arginine residues, such as tryptic peptides, their product-ion spectra contain also prominent  $[y_n + H + Ag]^+$  ions that may be used to confirm the residues cleaved from the C terminus. The  $m/z$  value of the  $[b_n - H + Ag]^+$  ion and that of the corresponding  $[y_n + H + Ag]^+$  ion resulting from cleavage of the same peptide bond are linked by the following relationship:  $[y_n + H + Ag]^+ = [M + Ag]^+ + Ag^+ - [b_n - H + Ag]^+$ . The observation of the corresponding  $[y_n + H + Ag]^+$  ions increases the confidence of the assignment for these peptides." Chu concludes: "The triplet search of  $[b_n + OH + Ag]^+$ ,  $[b_n - H + Ag]^+$ , and  $[a_n - H + Ag]^+$ , augmented by the confirmatory search for the corresponding  $[y_n + H + Ag]^+$  ions, appears to be a viable strategy for semiautomated residue sequencing from the C terminus of an oligopeptide. Protein identification via a sequence-tag search program designed for protonated peptides has been demonstrated using  $m/z$  values of protonated ions corresponding to the observed argentinated ions." This meets the limitations of the pending claims.

This document was publicly available 5/27/1999, (world wide web publication date) which is more than a year prior to the filing of the instant application, and the document comprises a differing inventive entity than the instant application.

### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

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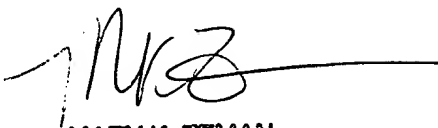
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz

5/23/03

  
MARY K. ZEMAN  
PRIMARY EXAMINER  
